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EXAMINER	
KIM, VICKIE Y	

ART UNIT	PAPER NUMBER
1614	8

DATE MAILED: 12/22/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/000,113	Applicant(s) SCHOENHARD, GRANT L.	
	Examin r Vickie Kim	Art Unit 1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-393* is/are pending in the application.

4a) Of the above claim(s) *1-362,370-372 and 377-393* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) *363-369 and 373-376* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election acknowledged

Applicants' election with traverse the group IX, claims 362-369 and 373-376 is acknowledged. Applicants' election of species, an antidepressant as a species of non-opioid CNS-active agents and nalmefene as a species of opioid receptor antagonist are acknowledged. Applicants traverse the election requirement without an argument. As mentioned in the previous office action, each group contains patentably distinct invention and the species are not necessarily sharing same chemical generic(core) structure(or pharma-core). Because a combination drug is not obvious over a combination drug containing different materials(species) under USC 103, a combination drug is considered to be a patentably distinct over other combination drug.

The traverse is not accepted, as not all invention/species encompassed by the genus would be classified together. Furthermore, even if there were unity of classification, the search of the entire genus in the non-patent(a significant part of a thorough examination) would be burdensome. Therefore, the election requirement is maintained, and made FINAL.

Claims 1-393 are now pending and the elected claims 362-369 and 373-376 have been examined only to the extent that they read on use of the elected species in the claimed method. All remaining(or portions thereof) not drawn to the elected species are withdrawn from further consideration as being non-elected. The following rejections are made.

Claim Objections

1. Claim 375 is objected to because of the following informalities: Halcyon recited in the claim 375 is misspelled. This is considered to be inadvertent typographical error. The correct spelling of said term is Halcion®. Appropriate correction is required.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claim 375 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 375 contains the trademark/trade name (i.e. Valium®, Ambien® or Halcion®). Where a trademark or trade name is used in a claim as a limitation to identify or describe a particular material or product, the claim does not comply with the requirements of 35 U.S.C. 112, second paragraph. See *Ex parte Simpson*, 218 USPQ 1020 (Bd. App. 1982). The claim scope is uncertain since the trademark or trade name cannot be used properly to identify any particular material or product. A trademark or trade name is used to identify a source of goods, and not the goods themselves. Thus, a trademark or trade name does not identify or describe the goods associated with the trademark or trade name. In the present case, the trademark/trade name is used to identify/describe diazepam, zolpidem or triazolam, respectively and, accordingly, the identification/description is indefinite.

Furthermore, it should be capitalized wherever it appears and be accompanied by the generic terminology. Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

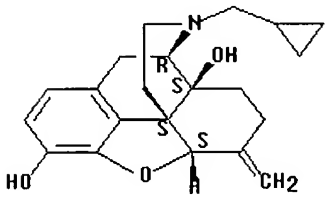
The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

4. Claims 362-369, 373-374 and 376 are rejected under 35 U.S.C. 102(b) as being anticipated by Dante (US5856332 or 5817665).

The claims are drawn to a composition comprising a combination of a non-opioid CNS-active agent such as an antidepressant(e.g. lithium) and an opioid receptor antagonist such as nalmefene.

US'332 or US'665 teaches a composition comprising a pharmacologically effective dose of an opioid antagonist(e.g. nalmefene) and a pharmacologically effective dose of at least one tricyclic antidepressant, see claim 6(US'332) or claim 9(US'665), respectively.

As to the claims 363, 369 and 376, nalmefene has the structure as following:



As to the claims 365-366, the limitations(i.e.ABC drug transporter, PGP (PGP1a) drug transporter) required by the instant claims are inherently possessed feature by the opioid inhibitor(e.g nalmefene).

Thus, all the critical elements required by the instant claims are taught by the cited reference. The claimed subject matter is not considered to be patentably distinct over the prior art of the record.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. Claim 375 is rejected under 35 U.S.C. 103(a) as being unpatentable over Dante (US5856332 or 5817665) in view of Dante (US 6034091).

The claim 375 further requires lithium, Valium®(diazerpam), Halcion® (triazolam), or Ambien®(zolpidem) as the effective species of said antidepressant.

As mentioned in 102 rejection(supra), Dante(US'332 or US'665 hereafter) teaches a composition comprising a pharmacologically effective dose of an opioid antagonist(e.g. nalmefene) and a pharmacologically effective dose of at least one tricyclic antidepressant, see claim 6(US'332) or claim 9(US 665).

Applicant's claim differs because The claim 375 further requires lithium, Valium®(diazerpam), Halcion® (triazolam), or Ambien®(zolpidem) as the effective species of said antidepressant. The claim 375 requires a composition comprising both ingredients(lithium or valium®; and nalmefene) together.

Although US'332 or US'665 does not contemplate the example of a composition containing both ingredients together, Dante's patent already teaches the use of nalmefene in combination with lithium(col. 4, lines 20).

US'091 , at column 8(especially claim 5), teaches the patented invention(treatment of depression) is achieved by administering an opioid antagonist(e.g. nalmefene) and an antidepressant that includes not only a tricyclic or a non-tricyclic antidepressant but also lithium where the combination is administered in a pharmaceutically acceptable carrier.

Thus, it would have been obvious to one of ordinary skill in the art at the time of the invention was made to make such modification (substitution a tricyclic or a non-

tricyclic antidepressant(US'332&'665) with lithium(US'091) because they are functional equivalent to each other as suggested in US'091.

One would have been motivated to do so, with reasonable expectation of success because it is always desirable to have extended therapeutic modalities to improve patient's compliance by enhancing patient satisfaction and increasing the selection option. The techniques and skills required for making such substitution is conventional knowledge or well within the skills of ordinary artisan as evidenced by Dante(US'091), see claims 1, 2 and 5.

Although the instant claims use the different names for the said ingredients than those taught in the cited references, these references are particularly pertinent and relevant because all the claimed species and their roles are well taught in the cited reference. Thus, one would have been motivated to combine these references and make the modification because they are drawn to same technical fields (constituted with same ingredients and share common utilities, and pertinent to the problem which applicant concerns about. MPEP 2141.01(a).

Conclusion

7. No claim is allowed.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vickie Kim whose telephone number is 703-305-1675. The examiner can normally be reached on Tuesday-Friday. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel can be reached on 703-308-4725. The fax phone numbers for the organization where

this application or proceeding is assigned are 703-746-3165 for regular communications and 703-746-3165 for After Final communications. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

Vickie Kim,
Primary Patent Examiner
Art unit 1614